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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,341	06/21/2005	Scott Eugene Conner	X-15463	1424
25885 7599 0620/2008 ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			EXAMINER	
			CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	
			NOTIFICATION DATE	DELIVERY MODE
			06/20/2008	ELECTRONIC .

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail  $\,$  address(es):

patents@lilly.com

# Application No. Applicant(s) 10/540,341 CONNER ET AL Office Action Summary Examiner Art Unit YONG CHU 1626 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 20 March 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 2.35-37.41-44.54.56-58.68 and 69 is/are pending in the application. 4a) Of the above claim(s) 42 and 56-58 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 2,35-37,41,43,44,54,68 and 69 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

PTOL-326 (Rev. 08-06)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/20/2008.

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

Art Unit: 1626

## DETAILED ACTION

Claims 2, 35-37, 41-44, 54, 56-58, 68 and 69 are currently pending in the instant application. Claims 42 and 56-58 remain withdrawn as non-elected subject matter.

Therefore, 2, 35-37, 41, 43-44, 54, 68 and 69 will be examined on the merits.

### Information Disclosure Statement

Applicants' Information Disclosure Statement, filed on 03/20/2008 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

#### Response to Amendment

The amendment by Applicants' representative MaCharri Vomdran-Jones dated on 03/20/2008 has been entered.

#### Response to Arguments/Remarks

#### Rejection of claims 52 and 53 under 35 U.S.C.§112

Applicants have cancelled the rejected claims 52 and 53. The rejection is moot.

## Rejection under 35 U.S.C.§102(a)/(e)

Applicant's amendment over the rejected claims 2, 35-37, 41, 43-44, 54 under 35 U.S.C.§102(a)/(e) does not overcome the rejection. It is because the claimed scope of the invention having R32 as C1-C6alkyloxo and U as an aliphatic linker with one carbon replaced with O is stilled anticipated by the prior art compounds ('the 858 application) cited in the previous Office action. Therefore, the rejection is maintained.

# Rejection under 35 U.S.C.§103(a)

Art Unit: 1626

Applicant's amendment and argument over the rejected claims 2, 35-37, 41, 43-44, and 54 *under 35 U.S.C.§*103(a) does not overcome the rejection. It is because the claimed scope of the invention having **R32** as C1-C6alkyloxo and **U** as an aliphatic linker with one carbon replaced with O is stilled anticipated by the prior art compounds (the '858 application) cited in the previous Office action. Therefore, the rejection is maintained.

The new claims 68 and 69 are also rejected *under 35 U.S.C.*§103(a) as obvious over the same prior art teaching ('the 858 application) cited in the previous Office

action. Claim 68 claims the elected species of the compound

and claim 69 claims the compound

,which are useful for treating

diabetes. The cited `858 application teaches a class of compounds, which structurally are so close to the instantly claimed compounds. The prior art teaches that the compounds are used for the same application, namely, treating diabetes. In addition to the previously cited prior art compounds, there are more compounds are also structurally so related to the instantly claimed compounds, such as (CAS RN 628335-

Art Unit: 1626

is H, -CH<sub>3</sub> vs. -Pr, or –Et, and such difference is suggested by the prior art. Applicants' argument of unobviousness between the '858 application and the instantly claimed compounds based on the recent Court ruling <u>Takeda Chemical</u> v. Alpharpharm, 492 F.3d1350, 83 U.S.P.Q.2D 1169 (2007) has been considered but is found not persuasive. The prior art teaching is very comprehensive, and very detail on the making and using the specific compounds for treating diabetes. The instantly claimed compounds are used for <u>treating the same disease</u>. The prior art does not need to disclose every compound in their specification, but a clear scope of invention with structurally closely related compounds. To one ordinary skilled in the art, the prior art as whole provides enough teaching, suggestion, and motivation leading to the instant invention. Therefore, new claims 68 and 69 are rejected *under 35 U.S.C.*§103(a).

# Claim Objections

Applicant's amendment by removal of the non-elected subject matter has obviated the objection.

#### Conclusions

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1626

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

# Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M<sup>e</sup>Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Application/Control Number: 10/540,341 Page 6

Art Unit: 1626

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./ Patent Examiner Art Unit 1626 /Kamal Saeed, Ph.D./ Primary Patent Examiner Art Unit 1626